



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0144; FRL-9972-94]

Assignment and Application of the “Unique Identifier” under TSCA Section 14; Notice of Additional Information and Opportunity to Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Recent amendments to the Toxic Substances Control Act (TSCA) require EPA to develop a system to assign a “unique identifier” whenever it approves a Confidential Business Information (CBI) claim for the specific chemical identity of a chemical substance, to apply this unique identifier to other information concerning the same substance, and to ensure that any nonconfidential information received by the Agency identifies the chemical substance using the unique identifier while the specific chemical identity of the chemical substance is protected from disclosure. EPA previously requested comment on approaches for assigning and applying unique identifiers, and has developed an additional approach on which it now requests comment.

DATES: EPA will accept written comments and materials submitted to the docket on or before *[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0144, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jessica Barkas, Environmental Assistance Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 250-8880; email address: *barkas.jessica@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you have submitted or expect to submit information to EPA under TSCA. Persons who would use unique identifiers assigned by the Agency to seek information may also be affected by this action. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers, importers, or processors of chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

A. TSCA Section 14 Requirement to Assign a “Unique Identifier”

The June 22, 2016, amendments to TSCA by the Frank R. Lautenberg Chemical Safety for the 21st Century Act added a requirement in TSCA section 14(g)(4) for EPA to, among other things, “assign a unique identifier to each specific chemical identity for which the Administrator

approves a request for protection from disclosure.” EPA is required to use the “unique identifier assigned under this paragraph to protect the specific chemical identity in information that the Administrator has made public” and to “apply that identifier consistently to all information relevant to the applicable chemical substance,” including “any nonconfidential information received by the Administrator with respect to a chemical substance . . . while the specific chemical identity of the chemical substance is protected from disclosure.” 15 U.S.C. 2613(g)(4).

The requirements to assign a unique identifier and the unreconciled requirements concerning application of the unique identifier and protection of CBI are more fully discussed in the **Federal Register** document published previously. (See 82 FR 21386; May 8, 2017; hereafter “May 8 **Federal Register** document”.) EPA has noted drawbacks to each of the two alternative approaches discussed in the May 8 **Federal Register** document.

EPA has developed a third alternative approach for reconciling the competing requirements of TSCA section 14(g), and now invites public comment on this new alternative.

A brief explanation of CBI claims for chemical identity provides context for understanding the potential effects of applying a unique identifier. TSCA section 14 permits a person to assert a CBI claim to seek to protect from public disclosure certain information in a submission, including a specific chemical identity. A CBI claim for specific chemical identity is intended to protect from disclosure the existence of the chemical substance and/or the fact that the chemical substance is (or is intended to be) manufactured by any person for commercial purposes in the United States (note that under TSCA, the term “manufacture” includes import).

When a chemical identity on the TSCA Inventory (Inventory) is claimed as CBI, then the chemical substance is maintained on the confidential portion of the Inventory. Conversely, a specific chemical identity that appears on the public portion of the Inventory, and is therefore known to be (or to have been) manufactured for commercial purposes in the United States, is generally not eligible for confidential protection (see, e.g., Chemical Data Reporting regulations at 40 CFR 711.30(b)). If another company reveals that they manufacture the substance for commercial purposes, such as in a non-CBI submission filed under TSCA, the chemical identity is no longer eligible for confidential protection, and a CBI claim for chemical identity would be denied upon evaluation. Because the meaning of a CBI claim for chemical identity is limited, companies that wish to protect other information in a submission (such as company identity or specific information regarding the use, function, or application of that chemical substance) should claim that specific information as CBI rather than (or in addition to) chemical identity.

B. Third Alternative Approach

Under this approach, EPA would assign one unique identifier (UID) per chemical substance. In most cases EPA would apply the UID to all non-confidential information concerning the same chemical substance, from any company. However, in a small number of cases, EPA would not apply the UID to some non-confidential documents, in order to preserve approved CBI claims for specific chemical identity where the non-confidential document itself does not undermine the

CBI claim, but EPA's application of the UID to that document would result in a linkage that does undermine the CBI claim. The basic criterion for application of the UID to submissions made by different submitters is that *the Agency's act of applying the UID must not disclose to the public the confidential specific chemical identity that the UID was assigned to protect.*

Specifically, prior to applying a UID to public versions of documents concerning the same substance, and filed by different submitters, those documents would be reviewed for presence of the specific chemical identity. If the specific chemical identity (e.g., Chemical Abstracts Service (CAS) name or CAS number) appears in any of the documents, EPA would revisit the CBI claim in the remaining document(s) to assure that the claim is unexpired and otherwise still valid. If the CBI claim remains valid, EPA would not apply the UID to the document that reveals the specific chemical identity, in order to preserve the CBI claim in the other document(s) (if the claim has expired, been withdrawn, or appears no longer valid, EPA would act in accordance with section 14(f)(2)(B) and/or 14(g)(4)(D), as appropriate). All of the documents would be available to the public, and the specific chemical identity would be revealed in the document where it was not claimed as CBI—the document revealing the specific chemical identity would simply not be connected by the UID to the other document(s) where the specific chemical identity is CBI.

For example, Company A files a Premanufacture Notice (PMN) and later, a Notice of Commencement (NOC), claiming chemical identity as CBI to protect from disclosure the fact that the chemical is now being manufactured for commercial purposes in the United States and hence is being added to the Inventory. EPA approves the CBI claim and assigns a UID. Company A subsequently files a section 8(e) notice concerning the same substance, claiming chemical identity as CBI again. The UID is applied to that submission as well. Sometime later, Company B files a section 8(e) notice on the same substance, which it asserts it is using for research and development (R&D) purposes, but does not claim chemical identity as CBI. EPA revisits Company A's original CBI claim and confirms that it is not expired, has not been withdrawn, and has not been denied. Company B's submission does not reveal that the substance is on the Inventory or that it is in commerce (as other than an R&D substance). If EPA applied the UID to Company B's submission, that act would link Company B's section 8(e) notice to Company A's NOC, revealing that the specific chemical identity in Company B's section 8(e) notice is also the subject of an NOC and has therefore been manufactured for commercial purposes, and is on the Inventory. Thus, EPA's linkage of the two documents through the applied UID—as opposed to any information contained in the non-confidential document itself—would undermine the previously approved CBI claim for chemical identity. EPA would not apply the UID to Company B's submission in this case, to preserve Company A's CBI claim.

By way of contrast, if Company B's non-confidential section 8(e) notice itself revealed that the chemical substance was manufactured for commercial purposes in the United States—for instance, if the filing were an incident report relating to the commercial manufacture or use of that chemical substance, as opposed to an R&D exploration as originally described—then this would indicate that Company A's CBI claim may no longer be valid, and EPA would reevaluate

the prior CBI claim in accordance with TSCA section 14(f)(2)(B) and/or 14(g)(4)(D), as appropriate.

EPA expects that exceptions to application of the UID will be fairly rare. For example, in reviewing all non-confidential section 8(e) submissions submitted over the past 5 years that included a CAS number (such that Inventory status can be readily checked), EPA found that fewer than 4% of these submissions mentioned substances that are currently on the confidential portion of the TSCA Inventory. Further, on preliminary review (i.e., without completing a full CBI review and determination), it appeared that several of these submissions were under circumstances indicating that the original CBI claim may have been withdrawn or otherwise became invalid, suggesting that there may be even fewer exceptional cases once EPA revisits the original CBI claim(s).

EPA acknowledges that this approach would occasionally create the possibility that the application of the UID to submissions from two or more companies may alert each company to the other's manufacture of the same chemical substance. However, such disclosures frequently arise in the normal course of business under TSCA, independent of UID. One reason for this is that a single accession number is typically assigned to each Inventory substance, and the accession number is often used for subsequent reporting, e.g., under the Chemical Data Reporting (CDR) rule. Accession numbers are also included alongside other regulatory information, such as relevant section 5 significant new use rule (SNUR) citations, reported in public databases, such as the Substance Registry Service (SRS), and in the Inventory file that EPA makes available to the public (confidential inventory chemicals are listed by PMN number, accession number, and generic name). (See <https://www.epa.gov/tsca-inventory/how-access-tsca-inventory>.) Anyone that has an accession number for a given confidential inventory substance can query the CDR database and learn whether other companies have manufactured the chemical in CDR-reportable amounts, or query the public Inventory to find out the PMN number of the original submission.

While not every company reports under the CDR for every chemical that they manufacture (for example, specialty chemical companies may be making relatively small quantities of a substance, for a specialized use, and may not meet the reporting thresholds for CDR), the fact that a chemical substance is on the Inventory can be revealed in other ways. For example, a company that intends to manufacture a chemical substance for commercial purposes may file a bona fide submission under 40 CFR 720.25 to determine whether the chemical substance is already on the Inventory. The response to the bona fide inquiry, where EPA tells the submitter whether a chemical substance is on the confidential portion of the Inventory, would indicate whether another company has manufactured the chemical substance for commercial purposes in the United States. Also, submitters of section 5 notices that are subsequently deemed to be invalid because the substance is already on the Inventory and thus not subject to section 5 reporting requirements are informed of the Inventory status and are provided the accession number.

This third alternative approach would avoid several problems that EPA has identified with assigning more than one UID to a single substance (see “Second Alternative Approach,” May 8 **Federal Register** document (at 21389). One such problem is that assigning more than one UID per chemical substance would work against one of the purposes of assigning UIDs, to “provide a specific reference identifier that protects the confidentiality claim to the specific chemical identity for the duration of the claim, while providing a way for the public to identify other filings pertaining to that substance.” (See discussion in EPA’s May 8 **Federal Register** document (at 21388).) In addition, it is unclear how multiple UIDs per chemical can be reconciled with the section 8(b)(7) requirement to publish and keep current a list of each confidential inventory chemical, with its UID, accession number, generic name, and PMN number, where applicable. Any list that includes all of this information for each chemical would automatically link submissions from different companies by including all of the UIDs and/or by using the same accession number for multiple listings on the same chemical. (i.e., if Chemical X has three UIDs, assigned to three different company claims, they would all be linked on this list, because Chemical X only has one accession number, and the list is supposed to include both accession number and UID.) It is also unclear to EPA how using one UID per chemical, per company, would operate in the case that a company or parts of a company changes ownership; how such UIDs would be applied to EPA-generated documents that are relevant to more than one submission; or how the multiple UIDs would be handled in the case that one company withdraws or permits its CBI claim to expire while the other does not. Using one UID per chemical, and applying that same UID to related documents in all but a very few exceptional cases, would avoid these issues.

C. Opportunity to Comment on Approach to Applying the Unique Identifier

EPA invites comment on the possible approach outlined above.

Authority: 15 U.S.C. 2613.

Dated: January 26, 2018.

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and Pollution Prevention.*

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